

Appl. No. 10/631,371
Response dated March 13, 2007
Reply to Office Action of December 15, 2006

LISTING OF CLAIMS:

Claims 1-24. (Cancelled)

Claim 25. (Currently Amended) A therapeutic method comprising providing to a patient in need of tranexamic acid therapy an ingestible solid pharmaceutically acceptable formulation comprising a therapeutic dose of tranexamic acid and at least one excipient wherein the excipient retards tranexamic acid release in the stomach and substantially releases tranexamic acid in the small intestine thereby reducing the concentration of tranexamic acid in the stomach during therapy and reducing adverse gastrointestinal side effects.

Claim 26. (Canceled)

Claim 27. (Original) The method of claim 25, wherein the at least one excipient controls release of tranexamic acid in the stomach.

Claim 28. (Canceled)

Claim 29. (Original) The method of claim 25, wherein the therapeutic dose is in the range of about 375 mg tranexamic acid to about 1 gram tranexamic acid per dose.

Claim 30. (Original) The method of claim 25, wherein the dose is administered three times a day or four times a day.

Claim 31. (Original) The method of claim 30, wherein the dose is at least two solid tablets or one sachet containing granules.

Claim 32. (Currently Amended) A therapeutic method comprising providing tranexamic acid therapy to a patient in need thereof in a pharmaceutically acceptable oral formulation comprising at least one excipient sufficient to provide release of the tranexamic acid in both the stomach and intestines such that a bolus of the tranexamic acid does not reach the lining of the stomach and intestines resulting ~~result~~ in a decreased stomach concentration of tranexamic acid after oral ingestion and thereby decreasing at least one gastrointestinal adverse effect of said therapy.

Claim 33. (Currently Amended) The method of claim 32, comprising, decreasing a gastrointestinal adverse effect selected from the group consisting of nausea, vomiting, diarrhea, constipation, cramping, bloating, and combinations thereof.

Claim 34. (Currently Amended) The method of claim 32, provided to a patient having menorrhagia.

Claim 35. (Currently Amended) A method of reducing gastrointestinal adverse side effects comprising administering an effective amount of an extended release pharmaceutical composition comprising tranexamic acid and at least one agent that ~~controls release of~~ controllably releases tranexamic acid from the composition in the gastrointestinal tract resulting in release of the tranexamic acid in both the stomach and intestines thereby decreasing at least one gastrointestinal adverse effect of said therapy.

Claim 36. (Currently Amended) A method of reducing gastrointestinal adverse side effects comprising administering an effective amount of a composition comprising tranexamic acid in an oral administrable formulation selected from the group consisting of extended release, delayed release, and combinations thereof, wherein upon oral administration tranexamic acid is either:
i) controllably released from the composition in the gastrointestinal tract resulting in release of the tranexamic acid in both the stomach and intestines; or

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ii) substantially released in the small intestine,
thereby decreasing at least one gastrointestinal adverse effect of said therapy.

Claim 37. (Original) A method of reducing gastrointestinal adverse side effects comprising directing oral administration of an effective amount of a delayed release pharmaceutical composition comprising tranexamic acid and at least one agent that delays release of the tranexamic acid from the composition until the small intestine.